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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
JANSSEN, SHANNON L	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Continued

Election/Restrictions

Applicant's elected Group I, claims 1-9, with traverse in the reply filed on June 22, 2009 and further clarified on July 7, 2009.

Claims 10-21 and 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions, there being no allowable generic or linking claim.

Applicant's elected species of (a) a first fusion protein fragment: phage coat protein (claim 4) and a second fusion protein fragment: a protein encoded by a cDNA (claim 3), (b) interaction domain for a first protein: a leucine zipper domain (claim 6) and interaction domain for a second protein: a leucine zipper domain (claim 6), and (c) a translocation sequence for a first fusion protein: a Sec-dependent sequence (claim 7) and a translocation sequence for a first fusion protein: a Tat-dependent sequence (claim 8) without traverse in the reply filed on June 22, 2009 and further clarified in the response filed on July 7, 2009.

Claims 2 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. It is noted that the amendment to claim 7 to be directed to a protein translocation sequence which is transport-pathway independent renders the claim to be drawn to a non-elected species, and accordingly, the claim has been withdrawn.

Information Disclosure Statement

The information disclosure statement filed March 29, 2011 fails to comply with 37 CFR 1.97(c) because it lacks either a statement as specified in 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Withdrawn Rejections

The rejection of claims 1, 3-7, 9, and 21-35 under 35 U.S.C. 102(b) as being anticipated by Crameri et al. (Display of biologically active proteins on the surface of filamentous phages: a cDNA cloning system for selection of functional gene products linked to the genetic information responsible for their production, 1993, Gene, vol 137, pp 69-75) is withdrawn in view of the claim amendments.

Any rejection of claim 7 is withdrawn in view of the claim amendments and withdrawal of the claim from consideration.

Maintained Rejections

Claims 1, 3-6, 9, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crameri et al. (Display of biologically active proteins on the surface of filamentous phages: a cDNA cloning system for selection of functional gene products linked to the genetic information responsible for their production, 1993, Gene, vol 137, pp 69-75) and Weiner et al. (US Patent 6,335,178, granted January 1, 2002), as evidenced by Wu et al. (Membrane targeting and translocation of bacterial hydrogenases, 2000, Arch Microbiol, Vol 173, pp 319-324). The

text of this rejection can be found in the Office Action mailed March 31, 2011 and is herein incorporated by reference.

Claims 1, 3-6, 9, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crameri et al. (Display of biologically active proteins on the surface of filamentous phages: a cDNA cloning system for selection of functional gene products linked to the genetic information responsible for their production, 1993, Gene, vol 137, pp 69-75) and Georgiou et al. (US Patent 7,419,783, filed November 5, 2002, with benefit to provisional applications 60/404944, filed August 21, 2002, and 60/337452, filed November 5, 2001). The text of this rejection can be found in the Office Action mailed March 31, 2011 and is herein incorporated by reference.

Response to Arguments

The amendment filed May 31, 2011 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance because of the following reasons. Applicants' arguments are presented in Italics.

Applicants assert there would be no motivation to combine the references and that even if one did combine the references, one would not use two different translocation sequences (Reply, pp 16-17).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all the references teach proteins with translocation sequences relating to folding and transportation into the periplasmic space or extracellular matrix. In addition, Weiner et al. state:

"Such translocation offers a unique advantage over current methodologies for protein purification. Because the composition of culture medium can be manipulated, and because the periplasm contains only about 3% of the proteins of gram negative bacteria, expressed proteins which are translocated into the extracellular medium or into the periplasm are more likely to be expressed as functional soluble proteins than if they were translocated to cellular membranes or to the cytoplasm. Furthermore, translocation to the periplasm or to the extracellular medium following protein expression in the cytoplasm allows the expressed protein to be correctly folded by cytoplasmic enzymes prior to its translocation, thus allowing retention of the expressed protein's biological activity." (See col 10).

Therefore, one of skill in the art would have been motivated to utilize the Tat sequence taught by Weiner et al. in order to take advantage of the benefits taught by Weiner et al.

Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element (i.e.: the Tat translocation sequence taught by Weiner et al.) for another known element (i.e.: the PelB translocation sequence taught by Crameri et al.) because it would have yielded the predictable result of a folded protein. See *KSR International Co. v. Teleflex Inc.*, USPQ2d 1385 (U.S. 2007).

In addition, it is noted that the instant claims are currently directed to a protein mixture not a cell containing the protein mixture. Applicants' arguments appear to be directed to the intended use of the product rather than the product as instantly claimed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a cell containing the proteins, which are transported out of the cell) are not recited in the rejected

claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants are claiming a product, not a method of using the product.

In addition, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP § 2145 I.

Applicants assert that claim 1 implicitly discloses an in vivo system (Response, p 18).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an *in vivo* system) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims do not recite a protein mixture present *in vivo*. The instant claims are drawn to a protein mixture, which can be present in, e.g., a test tube or similar container.

Applicants appear to argue that Choi et al. is nonanalogous art (Response, p 18).

In response, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all of the cited references are drawn to various protein expression systems.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 10:00AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shannon L Janssen
SLJ

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1636